

In re Application of: Tamar HAREL et al
Serial No.: 10/804,560
Filed: March 18, 2004
Office Action Mailing Date: March 27, 2008

Examiner: Michael William Kahelin
Group Art Unit: 3762
Attorney Docket: 34487

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 52-55, 79-87, and 101-102 are in this Application.

Claims 52-54, 79, 81-86, 101, and 102 are rejected under 35 U.S.C. §102, or, in the alternative under 35 U.S.C. §103.

Claims 55, 79, 80, 87, and 102 are rejected under 35 U.S.C. §103.

Claims 52 and 82 are amended herewith.

Claim 86 is cancelled herewith.

Claims 103-108 are added herewith.

Interview

The applicants thank Examiner Kahelin for the telephone interview given to the applicants representatives, Maier Fenster, and Itzhak Yogev, and for the Interview Summary mailed September 3, 2008, and kindly request putting the interview summary on the record.

After reviewing some other pending applications, with claims that bear some similarity to the claims of this application, the applicants decided to take a line that was not discussed in depth in the interview.

The reviewed applications included: 09/914,889; 10/237,263; 10/526,708; and 10/570,576 (Attorney Docket Nos. 34481, 34482, 34490; and 34497 respectively).

Amendments To The Claims

New claims

Claims 103 to 109 are added herewith to further claim some embodiments of the present invention.

Claim 103 and claim 104 are supported at least by page 20 lines 12-17 of the application as filed, reading: "Optionally, said electric field is applied as a bi-phasic

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and charge balanced time varying field. Optionally, said electric field is applied for a short duration every period of time. Optionally, said period of time gives an application frequency of between 1 Hz and 15 Hz. Alternatively or additionally, said period of time gives an application frequency of about 5 Hz. Alternatively or additionally, said duration is less than 30 ms. Alternatively or additionally, said duration is about 10 ms."

Claim 105 is supported at least by claim 7 of the application as filed, reading: "A method according to claim 1, wherein said electric field is non-excitatory in that it does not substantially induce new bursts of islet activity in said pancreas."

Claim 106 is supported at least by page 56 lines 24-25 of the application as filed, reading: "Optionally, electrodes for electrifying the pancreas are attached to the stomach".

Claim 107 is supported at least by page 57 lines 5-6, reading: "Optionally, the pancreatic control signals are synchronized to the electrical activity of the stomach, for example to have a minimal effect on the stomach".

Claim 108 is supported at least by page 43 lines 20-23 of the application as filed, reading: "In one example of a relatively safe pulse series, as shown below, some types of electrical stimulation reduce high glucose levels but do not substantially reduce normal glucose levels."

Rejections under 35 U.S.C. 102 and 103

Independent claim 52

Independent Claims 52 stands rejected under 35 U.S.C. 102 as being anticipated by Houben (U.S. 5,919,216) or, in the alternative, under 35 U.S.C. 103 as being obvious over Houben in view of Klettner (US 5,031,617).

Claim 52 is amended to contain a limitation that the apparatus comprises a circuitry "which electrifies said at least one electrode for a short duration every period of time, such that the resulting application frequency is between 1 and 15 times per

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second". The amendment is supported at least by page 20 lines 12-14 of the application as filed, reading: "Optionally, said electric field is applied for a short duration every period of time. Optionally, said period of time gives an application frequency of between 1 Hz and 15 Hz."

The applicants respectfully contend that neither Houben nor Klettner teaches such a circuitry, and therefore, not all the claim limitations are taught by the cited art, and the claims are novel and non-obvious over the cited patents.

In more detail, Houben teaches a circuitry that electrifies the electrodes in a frequency lower than once per second. For example, in Fig. 2 the electrification is every 12 seconds (see column 5 line 50), which is an order of magnitude lower than the lowest repetition rate recited in the claim.

In Fig. 8A the pulses are given in a repetition rate of about one repetition every 2.5 seconds, which is also out of the claimed repetition rate. The teachings of Houben in Fig. 8A is further different from the teaching of claim 52 in that in Houben the electric field does not reduce elevated blood sugar, but rather reduces insulin secretion to treat hypoglycemia (see col. 8 line 30-31).

Klettner does not teach an implantable electrode, and teaches repetition rate of between twice and three times daily, which is many orders of magnitude less frequent than the smallest frequency recited in the claim.

In view of the above, the applicants respectfully contend that claim 52 is novel and non-obvious over Houben, Klettner, or any combination thereof.

Dependent claims 53-55, 78-87, and 101-107

All the dependent claims depend, directly or indirectly, on independent claim 52, discussed above, and are accordingly patentable at least for the virtue of being dependent on a patentable base claim.

Nevertheless, Applicants wish to draw the Examiner's attention to the further patentability of some dependent claims over Houben:

Claim 53 contains the limitation that "said circuitry is configured to over stimulate *in cases of doubt*" [emphasis added]. Houben does not teach or suggest this

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limitation. The Examiner referred the applicant to col. 7 lines 58, which is included in the following passage:

"At 68, the stimulus is timed and delivered, after which the routine determines at 78 whether glucose should be checked. For example, glucose can be checked every 1 or 2 minutes. If glucose is not to be checked, the routine returns to 68 for the next stimulus; if glucose is to be checked, the routine returns to block 39".

This passage does not teach what to do in case of a doubt. This passage teaches, at most, that glucose check is required at a frequency of every 1 or two minutes, and that between such checks Houben considers it safe to stimulate with his pulse.

It is noted that low glucose levels have immediate hazardous effect that may prevent the patient from functioning normally (or worse), while the effect of high glucose levels is less immediate and may be unnoticed by the patient. Therefore, in case of doubt, it was preferred to allow the patient to remain with high blood glucose for additional minute or two, than to let the patient suffer too low glucose levels.

Houben is silent regarding a case of doubt. Therefore, the applicants respectfully submit that at least the limitation of over-stimulating *in case of doubt* is not taught or suggested by any of the cited patents, and that the Examiner did not set forth a prima facie case of obviousness against claim 53.

New claim 104 contains the limitation that "said given period is shorter than 30ms".

The applicants respectfully submit that Houben is silent about the duration of each of the pulses, and in particular does not teach or suggest a pulse with the recited length. The applicants, on the other hand, taught that some pulses of a length in the selected range reduce glucose without increasing insulin level (see page 47 of the application as filed, first full paragraph).

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Klettner teaches much longer stimulations without relating to pulses at all, and also does not teach or suggest the limitation that claim 104 adds to claim 52.

In summary, the applicants respectfully submit that claim 104 is patentable over the cited patents, at least because none of the cited patents teaches or suggests the limitation that claim 104 adds to claim 52.

In view of the above amendments and remarks it is respectfully submitted that claims 52-55, 79-87, and 101-106 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,



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Date: September 25, 2008

Enclosures:

- Petition for Extension (Three Months)
- Request for Continued Examination (RCE)